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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : St. Goar et al.  
Serial No. : 10/635,776  
Filed : August 5, 2003  
Title : METHODS AND APPARATUS FOR CARDIAC VALVE REPAIR

Art Unit : 3732  
Examiner : Cary O'Connor  
Conf. No. : 1704

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

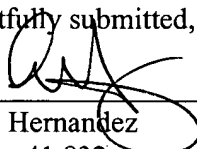
Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Form PTO-1449 (4 pages), cited non U.S. patent references, and return postcard for filing in connection with the above-captioned patent application.

- ☒ The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

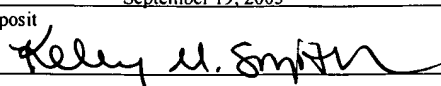
Date: September 19, 2005

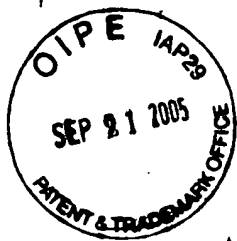
  
Fred C. Hernandez  
Reg. No. 41,832

**PTO Customer No.: 20985**  
Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-5625  
Facsimile: (202) 626-7796  
Email: fhernandez@fr.com

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Kelly M. Smith



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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (4 pages) and copies of the Foreign Patents and Non-Patent Literature are provided herewith in connection with the above-captioned application.

The documents listed on the Form PTO-1449 are in the English language with the exception of items BF, CC and CH. Item BF (Gateliene *et al.*) is in the Lithuanian language and is supplied with an English language summary attached to the article. Items CC and CH (Nakanishi *et al.* and Tamura *et al.*, respectively) are in the Japanese language and are provided with English language summaries attached to the article. Hence, in accordance with

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Kelly M. Smith

the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed item is necessary.

Applicant also makes known to the Examiner the following pending U.S. and International Applications that have one or more common inventors and/or are commonly owned:

<u>U.S.S.N.</u>	<u>Filing Date</u>	<u>Publication No.</u>	<u>Docket No.</u>
09/894,463	06/27/01	2002/0013571	020489-000400US
10/087,004	03/01/02	2003/0167071	20489-000500US
10/202,599	07/24/02	2002/0183766	20489-000310US
10/441,508	05/19/03	2004/0092962	20489-001500US
10/441,531	05/19/03	2004/0049207	20489-001400US
10/441,687	05/19/03	2004/0087975	20489-001700US
10/441,753	05/19/03	2004/0044350	20489-001200US
10/613,443	07/03/03	2004/0003819	20489-000120US
10/638,022	08/07/03	2004/0039442	20489-000130US
10/803,444	03/17/04	2004/0225300	20489-000410US
10/820,581	04/07/04	2005/0033446	17315-002002
10/877,279	06/24/04	2004/0236354	020489-000330US
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10/927,589	08/25/04	2005/0021057	020489-000150US
60/650,918	02/07/05	n/a	17315-004P01
11/058,957	02/15/05	2005/0149014	020489-001830US
60/674,931	04/25/05	n/a	17315-005P01
60/692,802	06/21/05	n/a	17315-004P02

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

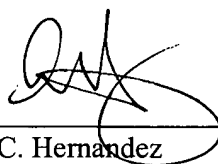
Applicant : St. Goar et al.  
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Filed : August 5, 2003  
Page : 3 of 3

Attorney's Docket No.: 17315-002001  
Supplemental Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing references and make them of record in the file history of the above-captioned application.

Respectfully submitted,

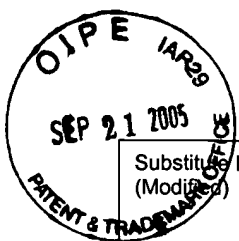
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Fred C. Hernandez  
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Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-5625  
Facsimile: (202) 626-7796  
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Substitute Form PTO-1449  
(Modified)U.S. Department of Commerce  
Patent and Trademark OfficeAttorney's Docket No.  
17315-002001Application No.  
10/635,776**List of Patents and Publications for Applicant's  
Information Disclosure Statement**Applicant  
St. Goar et al.Filing Date  
August 5, 2003Group Art Unit  
3732

(37 CFR §1.98(b))

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2002/0161378	10/31/02	Downing	606	108	06/15/01
	AB	2002/0183835	12/05/02	Taylor et al.	623	2.11	02/05/02
	AC	2003/0105519	06/05/03	Fasol et al.	623	2.1	09/04/98
	AD	2003/0187467	10/02/03	Schreck	606	150	03/26/02
	AE	2004/0097979	05/20/04	Svanidze et al.	606	151	11/14/02
	AF	2004/0158123	08/12/04	Jayaraman	600	37	02/02/04
	AG	2004/0236354	11/25/04	Seguin, J.	606	139	06/24/04
	AH	5,769,863	06/23/98	Garrison	606	148	12/16/96
	AI	6,575,971	06/10/03	Hauck et al.	606	52	11/15/01
	AJ	6,626,930	09/30/03	Allen et al.	606	213	05/01/00

**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AK	03/001893	01/09/03	PCT				
	AL	03/073913	09/12/03	PCT				
	AM	04/112585	12/29/04	PCT				
	AN	04/112651	12/29/04	PCT				
	AO	05/032421	04/14/05	PCT				
	AP	05/062931	07/14/05	PCT				

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	AQ	Agricola et al., "Mitral valve reserve in double orifice technique: an exercise echocardiographic study," Journal of Heart Valve Disease 11(5): 637-643 (2002)
	AR	Alfieri et al., "An effective technique to correct anterior mitral leaflet prolapse," J. Card. Surg. 14(6): 468-470 (1999)
	AS	Alfieri et al., "Novel suture device for beating heart mitral leaflet approximation," Annals of Thoracic Surgery 74: 1488-1493 (2002)
	AT	Alfieri et al., "The double orifice technique in mitral valve repair: a simple solution for complex problems," Journal Of Thoracic Cardiovascular Surgery 122: 674-681 (2001)

Examiner Signature

Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17315-002001	Application No. 10/635,776
<b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))		Applicant St. Goar et al.	
		Filing Date August 5, 2003	Group Art Unit 3732

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	AU	Alfieri, O., "Surgical Treatment of Atrial Fibrillation: Summary of Current Experience," The edge-to-edge repair of the mitral valve," [Abstract] 6th Annual NewEra Cardiac Care: Innovation & Technology, Heart Surgery Forum, pp. 103 (2003)
	AV	Alfieri, O., "The edge-to-edge repair of the mitral valve," [Abstract] 6 <sup>th</sup> Annual NewEra Cardiac Care: Innovation & Technology, Heart Surgery Forum, pp. 103 (2003)
	AW	Arisi et al., "Mitral valve repair with Alfieri technique in mitral regurgitation of diverse etiology: early echocardiographic results," Circulation Supplement II, 104: 3240 (2001)
	AX	Bhudia, S., "Edge-to-edge mitral repair: a versatile mitral repair technique," The Cleveland Clinic Foundation, Cleveland, Ohio, <a href="http://www.ctsnet.org/doc/7007">http://www.ctsnet.org/doc/7007</a> (accessed on December 14, 2004)
	AY	Borghetti et al., "Preliminary observations on haemodynamics during physiological stress conditions following 'double-orifice' mitral valve repair," European Journal of Cardio-thoracic Surgery 20: 262-269 (2001)
	AZ	Castedo, "Edge-to-edge tricuspid repair for redeveloped valve incompetence after DeVega's annuloplasty," Ann Thorac Surg. 75: 605-606 (2003)
	BA	Dottori et al., "Echocardiographic imaging of the Alfieri type mitral valve repair," Ital. Heart J. 2(4): 319-320 (2001)
	BB	Downing et al., "Beating heart mitral valve surgery: preliminary model and methodology," Journal of Thoracic and Cardiovascular surgery 123(6): 1141-1146 (2002)
	BC	Falk et al., "Computer-enhanced mitral valve surgery: toward a total endoscopic procedure," Seminars in thoracic and cardiovascular surgery 11(3): 224-249 (1999)
	BD	Fundarò et al., "Chordal placcation and free edge remodeling for mitral anterior leaflet prolapse repair: 8 year follow-up," Annals of Thoracic Surgery 72: 1515-1519 (2001)
	BE	Garcia-Rinaldi et al., "Left ventricular volume reduction and reconstruction is ischemic cardiomyopathy," Journal of Cardiac Surgery 14: 199-210 (1999)
	BF	Gateliene, "Early and postoperative results results of metal and tricuspid valve insufficiency surgical treatment using edge-to-edge central coaptation procedure," Medicina 38 (Suppl 2): 172-175 (2002) [Article in Lithuanian, English summary on page 174 of the article]
	BG	Gatti et al., "The edge to edge technique as a trick as a trick to rescue an imperfect mitral valve repair," Eur. J. Cardiothorac Surg 22(5): 817-20 (2002)
	BH	Gillinov et al., "Is minimally invasive heart valve surgery a paradigm for future?" Current Cardiology Reports 1: 318-322 (1999)
	BI	Gundry et al., "Facile Minimally Invasive Cardiac Surgery via Ministernotomy," Ann. Thorac. Surg. 65: 1100-1104 (1998)
	BJ	Ikeda et al., "Batista's operation with coronary artery bypass grafting and mitral valve plasty for ischemic dilated cardiomyopathy," The Japanese Journal of Thoracic and Cardiovascular Surgery 48: 746-749 (2000)
	BK	Izzat et al., "Early experience with partial left ventriculectomy in the Asis-Pacific Region," Annals of Thoracic Surgery 67: 1703-1707 (1999)
	BL	Källner et al., "Transaortic approach for the Alfieri Stitch," Ann Thorac Surg 71: 378-380 (2001)
	BM	Kavarna et al., "Transaortic repair of mitral regurgitation," Presented at the third annual New Era Cardiac Care conference, San Diego, CA, January 13-16 (2000), <a href="http://www.hsforum.com/vol3/issue1/2000-2389print.html">http://www.hsforum.com/vol3/issue1/2000-2389print.html</a> (accessed on December 14, 2004)

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				<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; vertical-align: top;">           Filing Date August 5, 2003         </td> <td style="width:50%; vertical-align: top;">           Group Art Unit 3732         </td> </tr> </table>	
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<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>					
Examiner Initial	Desig. ID	Document			
	BN	Kaza et al., "Ventricular reconstruction results in improved left ventricular function and amelioration of mitral insufficiency," <i>Annals of Surgery</i> 235(6): 828-832 (2002)			
	BO	Kherani, "The edge-to-edge mitral valve repair: the Columbia Presbyterian experience," <i>Ann. Thorac. Surg.</i> 78: 73-76 (2004)			
	BP	Konertz et al., "Results after partial left ventriculectomy in a European heart failure population," <i>Journal of Cardiac Surgery</i> 14(2): 129-135 (1999)			
	BQ	Kron et al., "Surgical relocation of the posterior papillary muscle in chronic ischemic mitral regurgitation," <i>Annals. of Thoracic Surgery</i> 74: 600-601 (2002)			
	BR	Krüger et al., "Edge to edge technique in complex mitral valve repair," <i>Thorac Cardiovasc Surg.</i> 48 (Supplement I): page 106 (abstract p73) (2000)			
	BS	Lorusso et al., "'Double-Orifice' technique to repair extensive mitral valve excision following acute endocarditis," <i>J. Card Surg</i> 13: 24-26 (1998)			
	BT	Lorusso et al., "The double-orifice technique for mitral valve construction: predictors of postoperative outcome," <i>Eur J. Cardiothorac Surg</i> 20(3): 583-589 (2001)			
	BU	Maisano et al., "The double orifice repair for Barlow Disease: a simple solution for a complex repair," <i>Circulation (Supplement 1)</i> 100(18): I-94 (1989)			
	BV	Maisano et al., "The double orifice technique as a standardized approach to treat mitral regurgitation due to severe myxomatous disease: surgical technique," <i>European Journal of Cardiothoracic Surgery</i> 17: 201-205 (2000)			
	BW	Maisano et al., "The hemodynamic effects of double-orifice valve repair for mitral regurgitation: a 3D computational model: a 3D computational model," <i>European Journal of Cardio-thoracic Surgery</i> 15: 419-425 (1999)			
	BX	Maisano et al., "Valve repair for traumatic tricuspid regurgitation," <i>Eur. J. Cardio-thorac Surg</i> 10: 867-873 (1996)			
	BY	Mantovani et al., "Edge-to-edge repair of congenital familial tricuspid regurgitation: case report," <i>J. Heart Valve Dis.</i> , 9(5): 641-643 (2000)			
	BZ	McCarthy et al., "Partial left ventriculectomy and mitral valve repair for end-stage congestive heart failure," <i>European Journal of Cardio-thoracic Surgery</i> 13: 337-343 (1998)			
	CA	Moainie et al., "Correction of traumatic tricuspid regurgitation using the double orifice technique," <i>Annals of Thoracic Surgery</i> 73: 963-965 (2002)			
	CB	Morales et al., "Development of an off bypass mitral valve repair," <i>The Heart Surgery Fourm #1999-4693</i> , 2(2): 115-120 (1999)			
	CC	Nakanishi et al., "Early outcome with the Alfieri mitral valve repair," <i>J. Cardiol.</i> 37(5): 263-266 (2001) [Abstract in English; Article in Japanese]			
	CD	Nielsen et al., "The edge-to-edge mitral repair: tension of the approximating suture and leaflet deformation during acute ischemic mitral regurgitation in the ovine heart," <i>Circulation</i> 104(Suppl 1): I-29-I-35 (2001)			
	CE	Osawa et al., "Partial left ventriculectomy in a 3 year old boy with dilated cardiomyopathy," <i>Japanese Journal of Thoracic and Cardiovascular Surgery</i> 48(9): 590-593 (2000)			
	CF	Privitera et al., "Alfieri Mitral Valve Repair: Clinical Outcome and Pathology," <i>Circulation</i> 106: 173 (2002)			
	CG	Redaelli et al., "A computational study of the hemodynamics after 'edge-to-edge' mitral valve repair," <i>Journal of Biomechanical Engineering</i> 123: 565-570 (2001)			
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	CH	Tamura et al., "Edge to edge repair for mitral regurgitation on a patient with chronic hemodialysis: report of a case," Kyobu Geka 54(9): 788-790 (2001) [Article in Japanese, English Summary]					
	CI	Timek, "Edge-to-edge mitral repair: gradients and three-dimensional annular dynamics in vivo during inotropic stimulation," European Journal of Cardio-thoracic Surgery 19: 431-437 (2001)					
	CJ	Timek, "Edge-to-edge mitral valve repair without ring annuloplasty for acute ischemic mitral regurgitation," Circulation 108 (Supplement II): II-122—II-127 (2003)					
	CK	Totaro, "Mitral valve repair for isolated prolapse of the anterior leaflet: an 11-year follow-up," European Journal of Cardio-thoracic Surgery 15: 119-126 (1999)					
	CL	Votta et al., "3-D computational analysis of the stress distribution on the leaflets after edge-to-edge repair of mitral regurgitation," Journal of Heart Valve Disease 11: 810-822 (2002)					

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